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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,801	05/30/2001	John W. Cherwonogrodzky	3929-3	5677

23117 7590 10/07/2005

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EXAMINER	
FORD, VANESSA L	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/866,801	Applicant(s) CHERWONOGRODZKY, JOHN W.
	Examiner Vanessa L. Ford	Art Unit 1645

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 June 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): Rejecton under 102(b) of claims 63-67 and 72..
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *NONE*.
   Claim(s) objected to: *NONE*.
   Claim(s) rejected: *63-65 and 67-80*.
   Claim(s) withdrawn from consideration: *83-86 and 88-90*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see Advisory attachment..
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: Advisory attachment.

Advisory Action Attachment

1. Applicants amendment and response filed June 21, 2005 is acknowledged. Claims 1-62, 66, 81-82, 87 and 91 have been cancelled.

Rejection Withdrawn

2. In view of Applicant's review and response the rejection of claims 63-67 and 72, pages 6-7, paragraph 5 of the Final Office action is withdrawn.

Rejections Maintained

3. The rejection under 35 U.S.C. 102(b) is maintained for claims 63-65, 67-73, 75-76 and 78-79 for the reasons set forth on pages 3-5, paragraph 4 of the Final Office Action.

The rejection was on the grounds that that Pasarell et al teach concentrated culture filtrate antigens that were obtained from the genera *Alternaria, Bipolaris, Curvularia, Dactylaria, Drechslera, Embellisia, Exserohilum, Fusarium, Helminthosporium, Microsporum, Scolecobasidium and Scopulariopsis.* Pasarell et al teach that the culture antigens were incubated and aerated on a rotating shaker (p. 1655, 2nd column). Pasarell et al teach that the concentrated culture filtrate antigens was used to immunize two New Zealand White female rabbits. Pasarell et al teach that an emulsion of 1 ml of each control antigen and 1 ml of Freund incomplete adjuvant was injected intramuscularly into the New Zealand rabbits. *Alternaria, Dactylaria, Drechslera, Embellisia, Fusarium, Micosporum, Scolecobasisum and Scolecobasidium and Scopulariopsis* did not have common antigens when tested against the antisera. Antigens of *Helminthosporium* only reacted with its own sera and there were no cross-reactions with any other antigens tested (p. 1656, 1st column). Pasarell et al teach that antisera prepared from *E. rostratum* recognized antigens prepared from *E. holmii.* Pasarell et al teach that a similar result was observed with antisera prepare from *E. mcginnisii* and *E. longirostratum*. Pasarell et al that common antigens are shared between the genera of *Bipolaris* and *Curvularia* (p. 1656). The process limitation of the supernatant being prepared and used at 20°C is a matter of design choice. Although

the reference appears to disclose the same cell culture supernatant claimed by the Applicants, the reference does not disclose the cell culture supernatant being prepared at the same temperature as the claimed process. However, the production of a cell culture supernatant by a particular process does not impart novelty or unobviousness to a cell culture supernatant when the same cell culture supernatant is taught in the prior art. This particularly true when properties of the cell culture supernatant are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). The fungal or yeast culture of Pasarell, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's fungal or yeast culture supernatant with the fungal or yeast culture supernatant of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i.e., that the fungal or yeast culture supernatant of the prior art does not possess the same material structural and functional characteristics of the claimed fungal or yeast culture supernatant). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the amendments are believed to obviate the rejection under 35 U.S.C. 102(b) of claims 63-65, 67-73, 75-76 and 78-79 as anticipated by Pasarell et al. Applicant urges that the Examiner indicated that the subject matter of claim 66 which was depended from 63 as patentable over Pasarell et al.

Applicant's arguments filed June 21, 2005 have been fully considered but they are not persuasive. It is the Examiner's position that the prior reference teaches the claimed invention. To address Applicant's comments regarding claim 66, it should be noted that Applicant has amended claim 63 to recited the claim limitation "for detecting anti-aflatoxin antibodies from a sample of a test subject...". It should be noted this claim limitation is a limitation of intended use since the claims are directed to an antigenic composition, which is a product. It should be remembered that a recitation of the intended use of the claimed invention must result in a structural difference between the

claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicant has provided no side-by-side comparison to show that the antigenic composition of the prior art differs from the claimed antigenic composition.

To address Applicant's regarding the patentability of claim 66, the Examiner did not reject claim 66 in the this rejection but did include claim 66 in other art rejections of record. There was no indication in the final office action that claim 66 was patentable over the prior art of record. Therefore, Pasarell et al anticipate the claimed invention.

4. The rejection under 35 U.S.C. 102(b) is maintained for claims 63-65, 67-68, 72, 74, 76 and 78-79 for the reasons set forth on pages 8-9, paragraph 6 of the Final Office Action.

The rejection was on the grounds that Groopman et al teach *Aspergillus* supernatant cultures which produce fungal aflatoxin (column 4) Groopman et al teach anti-aflatoxin antibodies (columns 5-6). Groopman et al et al teach vaccine compositions aflatoxins formulated in Freund's complete adjuvant which were used to immunize mice (columns 4-5) . The prior art teaches the claim limitation "wherein said supernatant displays specific antibody affinity such that only antibodies of a specific fungus or yeast bind to said components" since the prior art teaches that anti-aflatoxin are specific to *Aspergillus* (columns 5-6). The prior art also teaches the claim limitation "...composition for detecting levels of antibodies from a sample of a test subject" because the prior art teaches detecting and isolating aflatoxins in fluid samples (column 8). Although the reference appears to disclose the same cell culture supernatant claimed by the Applicants, the reference does not disclose the cell culture supernatant being prepared at the same temperature as the claimed process. However, the production of a cell culture supernatant by a particular process does not impart novelty or unobviousness to a cell culture supernatant when the same cell culture supernatant is taught in the prior art. This particularly true when properties of the cell culture supernatant are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC

1983); In re Brown, 173 USPQ 685 (CCPA 1972). Claims limitations such as "wherein said supernatant comprises a mixture of antigens which are capable of binding to different fungal or yeast species" and "wherein said components are capable of binding said antibodies" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's antigenic composition with the antigenic composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i.e., that the antigenic composition of the prior art does not possess the same material structural and functional characteristics of the claimed antigenic composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that Groopman et al fail to teach the claimed invention. Applicant urges that Groopman et al teach the production of antibodies which bind to aflatoxin. Applicant urges that Groopman et al do not teach a antigenic composition containing a cell culture supernatant according to the claimed invention. Applicant urges that Groopman et al do not literally or inherently suggest that the AFB_1 of the immunogen preparation is prepared according to the claimed invention. Applicant refers to Example 1 of Groopman et al to support the position that Groopman et al do not provide the claimed composition. Applicant urges that a method for preparing the tracer is not provided by Groopman et al.

Applicant's arguments filed June 21, 2005 have been fully considered but they are not persuasive. It is the Examiner's position that the prior reference teaches the claimed invention. Groopman et al teach an antigenic composition comprising a fungal cell culture supernatant. See column 4 of the prior art. To address Applicant's comments regarding the radio-labelled ^3H-alfatoxin B_1 tracer preparation method, it appears that Applicant is arguing limitations that are not in the claims. The claims are not directed to a method of preparing an antigenic composition. The claims are directed

to a antigenic composition comprising a fungal or yeast cell culture supernatant. The prior art teaches this product. To address Applicant's comments regarding Example 1, this example is directed to determining the affinity of anti-AFB_1 IgM antibody and not directed to the claimed invention. The claimed invention recites "an antigenic composition for detecting anti-aflatoxin antibodies from a sample of a test subject". It should be noted that this recitation is an limitation of intended use since the claimed invention is directed to a product. Applicant has provided no side-by-side comparison to show that the antigenic composition of the prior art differs from the claimed antigenic composition. Therefore, Groopman et al anticipate the claimed invention.

5. The rejection under 35 U.S.C. 102(b) is maintained for claims 63-65, 67-68, 73 and 78-80 for the reasons set forth on pages 9-11, paragraph 7 of the Final Office Action.

The rejection was on the grounds that Dubeau et al teach a *Chaetomium cellulolyticum* culture supernatant (see the Abstract). Although the reference appears to disclose the same cell culture supernatant claimed by the Applicants, the reference does not disclose the cell culture supernatant being prepared at the same temperature as the claimed process. However, the production of a cell culture supernatant by a particular process does not impart novelty or unobviousness to a cell culture supernatant when the same cell culture supernatant is taught in the prior art. This particularly true when properties of the cell culture supernatant are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Claims limitations such as "wherein said supernatant comprises a mixture of antigens which are capable of binding to different fungal or yeast species", wherein supernatant comprises aflatoxin", "wherein said components are capable of binding said antibodies" and "wherein said supernatant displays specific antibody affinity such that only antibodies of a specific fungus or yeast bind to said components " would be inherent in the teachings of the prior art. The claim limitation "composition for detecting levels of antibodies from a sample of a test subject" and "vaccine" are being viewed as a limitation of intended use.

Since the Office does not have the facilities for examining and comparing applicant's antigenic composition with the antigenic composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i.e., that the antigenic composition of the prior art does not possess the same material structural and functional characteristics of the claimed antigenic composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the amendments are believed to obviate the rejection under 35 U.S.C. 102(b) as anticipated by Dubeau et al. Applicant urges that the Examiner indicated that the subject matter of claim 66 which was depended from 66 as patentable over Dubeau et al.

Applicant's arguments filed June 21, 2005 have been fully considered but they are not persuasive. It is the Examiner's position that the prior reference teaches the claimed invention. To address Applicant's comments regarding claim 66, it should be noted that Applicant has amended claim 63 to recited the claim limitation "for detecting anti-aflatoxin antibodies from a sample of a test subject...". It should be noted this claim limitation is a limitation of intended use since the claims are directed to an antigenic composition, which is a product. It should be remembered that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicant has provided no side-by-side comparison to show that the antigenic composition of the prior art differs from the claimed antigenic composition.

To address Applicant's regarding the patentability of claim 66, the Examiner did not reject claim 66 in the this rejection but did include claim 66 in other art rejections of record. There was no indication in the final office action that claim 66 was patentable over the prior art of record. Therefore, Dubeau et al anticipate the claimed invention.

6. The rejection under 35 U.S.C. 102(b) is maintained for claims 63-64, 67, 70-72, and 77-78 for the reasons set forth on pages 11-12, paragraph 9 of the Final Office Action.

The rejection was on the grounds that Honbo et al teach *Cladosporium* culture supernatants (page 302). Honbo et al teach that the *Cladosporium* culture supernatants were formulated in Freund's. incomplete adjuvant and used to immunize rabbits (page 3030). Although the reference appears to disclose the same cell culture supernatant claimed by the Applicants, the reference does not disclose the cell culture supernatant being prepared at the same temperature as the claimed process. However, the production of a cell culture supernatant by a particular process does not impart novelty or unobviousness to a cell culture supernatant when the same cell culture supernatant is taught in the prior art. This particularly true when properties of the cell culture supernatant are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). The claim limitation "composition for detecting levels of antibodies from a sample of a test subject" is being viewed as a limitation of intended use.

Since the Office does not have the facilities for examining and comparing applicant's antigenic composition with the antigenic composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i.e., that the antigenic composition of the prior art does not possess the same material structural and functional characteristics of the claimed antigenic composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the amendments are believed to obviate the rejection under 35 U.S.C. 102(b) as anticipated by Honbo et al. Applicant urges that the Examiner indicated that the subject matter of claim 66 which was depended from 66 as patentable over Honbo et al.

Applicant's arguments filed June 21, 2005 have been fully considered but they are not persuasive. It is the Examiner's position that the prior reference teaches the claimed invention. To address Applicant's comments regarding claim 66, it should be noted that Applicant has amended claim 63 to recited the claim limitation "for detecting anti-aflatoxin antibodies from a sample of a test subject...". It should be noted this claim limitation is a limitation of intended use since the claims are directed to an antigenic composition, which is a product. It should be remembered that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicant has provided no side-by-side comparison to show that the antigenic composition of the prior art differs from the claimed antigenic composition.

To address Applicant's regarding the patentability of claim 66, the Examiner did not reject claim 66 in the this rejection but did include claim 66 in other art rejections of record. There was no indication in the final office action that claim 66 was patentable over the prior art of record. Therefore, Honbo et al anticipate the claimed invention.

Status of Claims

7. No claims are allowed.

Conclusion

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
September 27, 2005

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